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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/614,639

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Salvatore Albani

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04/23/2009

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EXAMINER

EWOLDT, GERALD R

ART UNIT

PAPER NUMBER

1644

NOTIFICATION DATE

DELIVERY MODE

04/23/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DOCKETING@BIOTECHNOLOGYLAWGROUP.COM

<b>Office Action Summary</b>	<b>Application No.</b> 10/614,639	<b>Applicant(s)</b> ALBANI, SALVATORE	
	<b>Examiner</b> G. R. Ewoldt, Ph.D.	<b>Art Unit</b> 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 March 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 15-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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#### DETAILED ACTION

1. Applicant's amendment and remarks filed 3/13/09 have been entered.

2. Claims 15-20 are under examination.

3. In view of Applicant's amendment the previous rejection under 35 U.S.C. 102(b) has been withdrawn.

4. Claim 19 is objected to. In line 5, "choler" should be "cholera".

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 15-20 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1 and 7 of U.S. Patent No. 6,787,154. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claim and the claims of the '154 patent, which recites an artificial APC with a molecule for binding to a solid support, differ only in that the instant APC further comprises a generic immunostimulatory molecule and is bound to a solid support. Said minor differences would be obvious to the ordinarily skilled artisan and do not render the device of the instant

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claims patentably distinct. Note that the 2/14/02 restriction of parent application 09/421,506 included a group comprising an immunomodulatory column (Claim 215), however, said column comprised numerous additional limitations not recited in the instant claim, thus, the instant device is obvious in view of the previously allowed artificial antigen presenting cell.

Applicant's arguments, filed 3/13/09, have been fully considered but are not found persuasive. Applicant makes the very curious argument that the invention of the '154 patent is a method whereas the invention of the instant claims is an article of manufacture. Applicant further makes the argument that an unnamed "PTO training personnel" "unofficially" informed Applicant that the rejection was improper.

It is unclear how anyone, and particularly a "PTO training personnel", could view the invention of the '154 patent as a method. Claim 1 is reproduced here:

1. An artificial antigen presenting cell, comprising:
  - a) a liposome comprising a lipid bilayer, wherein the lipid bilayer is comprised of neutral phospholipids and cholesterol;
  - b) at least one GM-1 ganglioside molecule disposed in the lipid bilayer;
  - c) a cholera toxin .beta. subunit bound to a GM-1 ganglioside molecule;
  - d) an MHC:antigen component, wherein said MHC:antigen component is bound to the cholera toxin .beta. subunit; and
  - e) an accessory molecule that can stabilize an interaction between a T cell receptor and the antigen-loaded MHC component.

Applicant is requested to identify the method steps in the claim set forth above. Applicant is also requested to provide the name of the "PTO training personnel" with whom the discussion took place for further clarification.

Applicant is further reminded of 37 CFR 1.2. The relevant portion is reproduced here:

§ 1.2 Business to be transacted in writing.

**All business with the Patent and Trademark Office should be transacted in writing.** The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. **No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.** (emphasis added)

It remains the Examiner's position that the invention of the '154 patent is a composition and not a method. Accordingly, the rejection has been maintained.

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6. No claim is allowed.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara, Ph.D. can be reached on (571) 272-0878.

9. **Please Note:** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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